

**REMARKS**

**Status of the claims**

Upon entry of this amendment, claims 1-7 and 10-12, and 15-20 will be pending, claims 8-9 and 13-14 being cancelled herein. Claims 1-2, 5, 6, 10, 16, and 18 are amended. Support for the amendments may be found in the specification as filed, *see, e.g.*, paragraphs [0011], [0016], [0047] and [0060].

**Response**

**Claim objections**

Applicants thank the Examiner for pointing out the discrepancies between the MISC\_FEATUREs of SEQ ID NOS:1, 2 and 28 in the sequence listing filed November 13, 2008 and as referenced in the specification as filed. Applicants also thank the Examiner for pointing out that SEQ ID NOS must be inserted after (Gly)<sub>n</sub> for n = 4 to 7 in paragraph [0066].

Submitted herewith is a replacement Sequence as a .txt file, which corrects the typographical errors of the MISC\_FEATUREs of SEQ ID NOS:1, 2, and 28 such that the sequences listed in the Sequence Listing are identical to the referenced sequences in the specification as filed. Accordingly, Applicants respectfully request the Examiner withdraw the objections based on the typographical errors in SEQ ID NOS: 1, 2, and 28 of the Sequence Listing submitted November 13, 2008.

The Sequence Listing herewith is submitted as a .txt file, which pursuant to 37 CFR § 1.824 comprises both the computer readable form (CRF) and the written file. The Sequence Listing information recorded in the CRF copy is identical to the written file and contains no new subject matter. The sequences contained herein were present in the application as originally filed. Applicants respectfully request that the examiner enter an amendment directing entry of the Sequence Listing into the application.

Claim rejections

The Examiner rejected claims 2 and 16-20 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention. In particular, the Examiner noted that SEQ ID NO:28 as defined in the Sequence Listing filed November 13, 2008 and as recited in claims 2 and 16 recite that the amino acid residues at positions 2-4 and 6-8 can be any D-stereoisomer amino acid. Attached herewith is a replacement Sequence Listing, which clarifies that amino acid residues at positions 2-4 and 6-8 of SEQ ID NO:28 are norLeucine, as described in paragraphs [0059] and [0060]. Accordingly, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 112, first paragraph is rendered inapposite. As such, Applicants respectfully request the Examiner withdraw the rejections on this basis.

The Examiner rejected claims 1-9 and 18 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In particular, the Examiner alleges that the recitation of "an affected subject" in claim 1 is unclear as to whether the claim requires treatment of a subject who already has the disease. Additionally, claim 18 is rejected for reciting that all the amino acids of the oligopeptide are the D-isomer. Without acquiescing to the Examiner's allegations, and solely for the purpose of expediting prosecution, claim 1 has been amended to recite that the subject is an interstitial cystitis-afflicted subject, and claims 6 and 18 have been amended to clarify that all of the amino acids other than glycine can be the D-isomer. Accordingly, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 112, second paragraph is rendered inapposite. As such, Applicants respectfully request the Examiner withdraw the rejections on this basis.

The Examiner alleged that claims 1-20 were not entitled under 35 U.S.C. § 119(e) to the benefit of the filing date of Provisional Application No. 60/426,684 (November 15, 2002). Applicants respectfully disagree. However, without acquiescing to the Examiner's allegation, and solely for the purposes of expediting prosecution, claims 1 and 10 have been amended to recite the oligopeptide

comprises the amino acid sequence set forth as SEQ ID NO:28, and the Sequence Listing has been corrected such that SEQ ID NO:28 sets forth the sequence of bc # 1nL as described in the specification (*see*, paragraph [0059]).

As amended, claim 1 recites a method of therapeutically treating interstitial cystitis, comprising administering to an interstitial cystitis-afflicted subject a pharmaceutically effective amount of a composition comprising an oligopeptide, wherein said oligopeptide comprises the amino acid sequence set forth as SEQ ID NO:28. Claim 10 recites a method of treating interstitial cystitis, comprising contacting tissue or cells affected by IC with a pharmaceutically effective amount of a composition comprising an oligopeptide comprising the amino acid sequence set forth as SEQ ID NO:28 to ameliorate a manifestation of interstitial cystitis.

U.S. Provisional Application No. 60/426,684 ("the '684 application) discloses bc # 1nL, and indicates that this oligopeptide may be used to treat interstitial cystitis, *see*, Table III and Example 1. The '684 application also indicates the disclosed oligopeptide may comprise a terminal amino acid that may be modified, e.g., amidated, may contain one or more D-isomer amino acids, and may be administered by intravesicle instillation, *see*, e.g., paragraphs [0031], [0034], [0108]. Furthermore, the '684 application discloses that interstitial cystitis involves mast cell activation and Substance P expression, while degradation of the urine/blood barrier is described as well in more detailed physiological terms, etc., *see*, e.g., '684 application at Background paragraph [0006] (stating "[Interstitial cystitis-A]ffected bladders show qualitative changes in mucosal glycosaminoglycan, ultrastructural defects in urothelium, and increased transport of urea. Pain and urgency occurs in a majority of patients with IC upon intravesical instillation with KCl solution, suggestive of compromised epithelial structure. Similarly, a urea solution instilled into the bladder and then later drained has lower urea concentrations in IC patients versus control groups, indicating increased mucosal permeability in affected subject.").

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In light of the above remarks, Applicants respectfully submit that the present application is entitled under 35 U.S.C. § 119(e) to the benefit of at least the filing date of Provisional Application No. 60/426,684, which is November 15, 2002.

The Examiner rejected claims 1 and 7-15 under 35 U.S.C. 102(a) as being anticipated by the Gonzalez et al abstract (J. Urology, Vol. 169, pages 68-69), and claims 2-6 and 16-20 as anticipated by the Gonzalez et al abstract in view of Gamache (U.S. Patent No. 7,026,296). Applicants note that the Gonzalez abstract was published in 2003, after the priority date claimed. Since the present application is entitled under 35 U.S.C. § 119(e) to the benefit of the filing date of November 15, 2002, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(a) is rendered inapposite. As such, Applicants respectfully request the Examiner withdraw the rejections on this basis.

The Examiner rejected claims 1, 3, 4, 5, 8, and 9 under 35 U.S.C. § 102(b) as being anticipated by WO Patent Application 98/46633. Applicants respectfully traverse, as there is no teaching or suggestion in the cited art of therapeutically treating a subject afflicted with interstitial cystitis as presently claimed. Accordingly, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(b) is rendered inapposite. As such, Applicants respectfully request the Examiner withdraw the rejections on this basis.

#### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims of the present application are in condition for allowance and early notification to that effect is respectfully requested.

An (3) month extension of time is hereby requested with payment of the requisite fees. The Commissioner is authorized to charge any fees associated with this communication, including any necessary fees for additional claims, and/or credit any overpayment to Deposit Account No. 50-4616.

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If the Examiner believes that there are further unresolved issues that could be resolved by discussion, the Examiner is respectfully requested to phone Todd A. Lorenz at (415) 318-1212.

Respectfully submitted,  
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By:   
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